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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,488	11/20/2003	Richard W. Armentrout	850136.422	3667

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EXAMINER

FERNANDEZ, SUSAN EMILY

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/718,488	Applicant(s) ARMENTROUT, RICHARD W.	
	Examiner Susan E. Fernandez	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed June 21, 2006, has been received and entered.

Claims 1-16 are pending. Claims 1-15 are withdrawn.

Claim 16 is examined on the merits to the extent it reads on the elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Rath et al. (J. Med. Microbiol., January 2001, 50: 108-109) in light of Greisen et al. (J. Clin. Microbiol., 1994, 32: 335-351).

Rath discloses a transport medium comprising gellan gum (0.75%, 0.1% MgSO₄ • 7 H₂O) (page 108, first column, third paragraph). In one experiment, swabs of bacterial reference strains were combined with a tube containing gellan gum (page 108, second column, second paragraph), and then the bacterial DNA was extracted by phenol-chloroform extraction and precipitation of DNA in isopropanol, followed by resuspension of the resulting pellet in water, as described on page 108, second column, first paragraph. PCR was performed on this sample according to the methods of Greisen et al. (page 108, second column, second paragraph). Specifically, the bacterial DNA (target nucleic acid) was amplified by combining the sample with a reaction mixture comprising deoxynucleoside triphosphates (dNTPs), and DNA

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polymerase (Greisen et al., page 336, first column, last paragraph). Thus, the resulting mixture is a composition comprising gellan gum 0.75%, water present in the gellan gum, the target nucleic acid, dNTPs, and DNA polymerase.

Applicant's arguments filed June 21, 2006, have been fully considered but they are not persuasive. Applicant asserts that the multiple references were improperly combined for a rejection under §102. As applicant properly noted, in a rejection under §102, an extra reference can be cited to show that a characteristic not disclosed in the primary reference is inherent. Greisen et al. is cited in the above rejection to indicate the presence of dNTPs and DNA polymerase when the PCR step was performed, as the primary reference specifically cited the PCR methods of Greisen et al. Therefore, the PCR methods of Greisen et al., including its use of dNTPs and DNA polymerase, are inherent in the experiments disclosed in Rath et al.

With respect to applicant's assertion that gellan is separated from the DNA when DNA extraction and precipitation occurs, it is respectfully pointed out that PCR was performed in gellan gum (see page 108, last paragraph through page 109, first paragraph, and Figure 1 on page 108). Therefore, gellan gum is clearly present in a composition comprising nucleic acid, DNA polymerase, and dNTPs. Thus, a holding of anticipation is clearly required.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

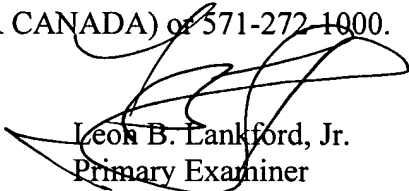
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan E. Fernandez
Assistant Examiner
Art Unit 1651



Leon B. Lankford, Jr.
Primary Examiner
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sef